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AUTHORITY: 41 U.S.C. 414; 48 CFR 1.301–1.304.

SOURCE: 75 FR 10570, Mar. 8, 2010, unless otherwise noted.

1335.001 Definitions.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (*i.e.*, the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

48 CFR Ch. 13 (10–1–14 Edition)

1335.006 Contracting methods and contract type.

(a) Insert provision 1352.235–70, *Protection of Human Subjects*, in all solicitations where research services under the contract might involve the use of human subjects. The provision is mandatory where human subjects may be used in performance of the award and may not be modified without consultation with Program Counsel.

(b) Insert clause 1352.235–71, *Protection of Human Subjects—Exemption*, in all contracts where the agency has determined based on documentation submitted by the offeror in response to provision 1352.235–70, *Protection of Human Subjects*, that the research involving human subjects is exempt from the requirements of 15 CFR part 27 and does not require Institutional Review Board (IRB) review. The provision is mandatory where an appropriate agency official has determined that the research involving human subjects to be carried out in performance of the award is exempt from 15 CFR part 27, and may not be modified without consultation with Program Counsel.

(c) Insert clause 1352.235–72, *Protection of Human Subjects—Institutional Approval*, in all contracts where the agency has determined based on documentation submitted by the offeror in response to provision 1352.235–70, *Protection of Human Subjects*, that the research involving human subjects is not exempt from the requirements of 15 CFR part 27 and requires review by a cognizant Institutional Review Board (IRB). The provision is mandatory where an appropriate Agency official has determined that the research involving human subjects to be carried out in performance of the award is not exempt from 15 CFR part 27 and requires review by a cognizant IRB, and may not be modified without consultation with Program Counsel.

(d) Insert clause 1352.235–73, *Protection of Human Subjects—After Initial Contract Award*, in all contracts where at the time of award no research involving human subjects is anticipated, but where decisions made in the course of the research may necessitate the addition of research involving human subjects to the work performed. The provision is mandatory where it is possible

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that the use of human subjects may be required in performance of the award but is not anticipated at the time of award, and may not be modified without consultation with Program Counsel.

1335.014 Government property and title.

The designee authorized to determine that the policies in FAR 35.014(b)(1)–(4) will not apply regarding title to equipment purchased by nonprofit institutions of higher learning and nonprofit organizations whose primary purpose is the conduct of scientific research is set forth in CAM 1301.70.

1335.016 Broad agency announcement.

1335.016-70 DOC procedures for the use of broad agency announcements.

Procedures for the use of broad agency announcements within the Department of Commerce are set forth in CAM 1335.016.

1335.017 Federal funded research and development centers.

1335.017-2 Establishing or changing an FFRDC.

The designee authorized to approve the establishment of an FFRDC, or change its basic purpose and mission, is set forth in CAM 1301.70.

1335.017-4 Reviewing FFRDCs.

The designee authorized to approve the continuation or termination of the sponsorship of an FFRDC is set forth in CAM 1301.70.

PART 1336—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

Subpart 1336.2—Special Aspects of Contract for Construction

Sec.

1336.203 Government estimate of construction costs.

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1336.609 Contract clauses.

1336.609-1 Design within funding limitations.

AUTHORITY: 41 U.S.C. 414; 48 CFR 1.301–1.304.

SOURCE: 75 FR 10570, Mar. 8, 2010, unless otherwise noted.

Subpart 1336.2—Special Aspects of Contracting for Construction

1336.203 Government estimate of construction costs.

After award, the independent Government estimated price can be released, upon request, to those firms or individuals who submitted proposals.

1336.270 Special requirements for ship construction

See 48 CFR 1371 for special requirements for acquisition involving ship construction and ship repair.

Subpart 1336.6—Architect-Engineer Services

1336.602 Selection of firms for architect-engineer contracts.

1336.602-2 Evaluation boards.

Permanent and *ad hoc* architect-engineer evaluation boards may include preselection boards. When necessary, members of permanent, *ad hoc*, and preselection boards may be appointed from private practitioners of architecture, engineering, or related professions. Private practitioners may be appointed as deemed necessary by the BPO or higher agency official. The permanent and *ad hoc* evaluation boards should be comprised of at least a majority of government personnel.

1336.602-4 Selection authority.

Each contracting office shall designate the selection authority based on the complexity of each procurement.